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TITLE: Development and Validation of a Theory Based Screening Process for Suicide Risk

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14. ABSTRACT The ultimate objective of this study is to assist in increasing the capacity of military-based health services to accurately identify persons at risk for suicide and to render effective referral dispositions. To do so we will characterize and evaluate the ability of a proposed suicide screening instrument and associated clinical decision-making algorithm to accurately identify at-risk individuals and provide appropriate treatment recommendations. Furthermore we will evaluate key theoretical questions related to distinguishing who is at most risk for actual suicide. After completing the IRB approval process from the University of Washington and receiving approval from HRRPO with MRMC headquarters oversight as indicated by the DoD Instruction 3216.02, recruitment at the SELF Center/PDHRA Clinic at JBLM began in September 2012. We successfully negotiated a subcontract with STRONG STAR Consortium researchers from University of Texas Health Sciences at San Antonio to collect data at the Ft. Hood site. We received permission from the SRP Command to recruit soldiers scheduled to attend the PDHRA interview process. We completed the Ft. Hood site IRB approval process (UW, HRPO/MRMC, UTHSCSA, BAMC) and began data collection at Ft. Hood in May 2013. Currently we have consented 663 subjects at JBLM, 102 at Ft. Hood, for a total of 765 subjects. Our recruitment target is 4,000 subjects. Due to various factors that have delayed our progress, the data collection and analyses phase of our study could not be completed by our contract end date. We have requested a one-year no-cost extension to complete the study					
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INTRODUCTION

The ultimate objective of this study is to assist in increasing the capacity of military-based health services to accurately identify persons at risk for suicide and to render effective referral dispositions. To do so we will characterize and evaluate the ability of a proposed suicide screening instrument and associated clinical decision-making algorithm to accurately identify at-risk individuals and provide appropriate treatment recommendations. Furthermore we will evaluate key theoretical questions related to distinguishing who is at most risk for actual suicide.

BODY

Accomplishing tasks in the time frame proposed in our original timeline has been challenging primarily due to the complexity of securing project sites, the unanticipated procedure of using the DoD Instruction 3216.02 for IRB approval, lower number of soldiers available to consent than previously anticipated at Ft. Lewis, and the PDHRA scheduling changes due to sequestration-required furloughs at Ft. Lewis, and maybe at Ft. Hood as well.

1. Secure Project Sites

We have received permission to recruit subjects and collect data at both JBLM and Fort Hood. Specific site status is described below.

JBLM

JBLM is fully on board with supporting us in conducting our study there. We have been collecting data since September 2012. We would like to highlight some of the milestones involved in this process. After numerous attempts to discern the appropriate individual(s) with whom to discuss our study, we were directed to Dr. Joseph Etherage, Programs and Research Chief at Madigan Army Medical Center, who in turn connected us with Dr. H. Quigg Davis, Chief at the Soldier Evaluation for Life Fitness Center where the PDHRA processing takes place at JBLM. Dr. Davis worked with us on recruitment protocol to ensure that our study could be conducted at the SELF Center with minimal impact on the PDHRA process. To conduct our research project at JBLM we received a letter of support from Lieutenant Colonel Mary Reed, Chief of the Department of Operational Medicine and Deployment Health at Madigan. Dr. Chienhua Clarke, who succeeded Dr. Davis as Chief, agreed to allow us to start recruiting units of soldiers who were scheduled for the PDHRA process in September 2012.

Fort Hood

Ft. Hood is also fully on board with supporting us in conducting our study there. We have been collecting data since May 2013. This site has been more complicated for us due to its distance from Seattle and thus the need to subcontract our research activities. We have negotiated a subcontract agreement with Dr. Alan Peterson, Director of the STRONG STAR Consortium, who has agreed to have his staff run our research study at Fort Hood. STRONG STAR has a long history of successful research activities at Fort Hood and is in an excellent position to be able to carry out our protocol. Colonel Bruce Crow and Dr. Bret Moore were involved in facilitating SRP connections for us at Fort Hood. In November 2012, we received letters of support from both COL Thomas Brooks, Medical Director of Ft. Hood's SRP, and LTC Sharette Gray, Chief of the Behavioral Health Department at Ft. Hood., for us to proceed recruiting soldiers at the SRP Center with the STRONG STAR/UTHCSA staff conducting our study.

2. Obtain approval from human subjects

Again, we would like to describe the major milestones involved in getting to our current position. After successfully going through the process of relying on the new DoD Instruction 3216.02 for JBLM earlier in 2012, we approached BAMC and MRMC for permission to follow the same route for Ft. Hood.

To recap, this new instruction allows for the non-engaged extramural research study funded by the DoD to have the local IRB (University of Washington) take responsibility for human subject protection issues with headquarters oversight from MRMC.

After discussions with Karen Eaton, a Human Subjects Protection Scientist at HRPO, and with Lynn Platteborze, a Human Protection Administrator at BAMC we proceeded with the steps for MRMC Headquarters approval. We received BAMC's determination for our study as a non-engaged extramural research study in February 2013. For Ft. Hood, we had the additional step of negotiating an IRB Authorization Agreement with UTHSCSA's OIRB. We received the signed agreement between UW's IRB and UTHSCSA's OIRB from Dr. David Weiss, Vice President for Research at UTHSCSA-OIRB, in March 2013. In April 2013, after submitting all the required documentation, we received MRMC Headquarters approval to begin recruiting soldiers at the Ft. Hood SRP Center.

3. Recruitment, consent & administration of initial screener and supplemental questionnaires

JBLM

We began recruiting soldiers scheduled at the Ft. Lewis SELF/PDHRA Clinic in September 2012. The flow of soldiers had been somewhat sporadic until the 2-2 and 3-2 Stryker Brigades were scheduled in February 2013 and May 32013, respectively. The number of soldiers available to consent has been lower than previously anticipated at the PDHRA Clinic due to administrative practices designed to avoid interruptions in the flow of soldiers to their providers. To date we have consented 663 of the 2151 soldiers approached to participate in our study (31%). We anticipate some smaller target groups scheduled for the PDHRA process in August. In mid September through December 2013 the 4-2 Stryker Brigade will be scheduled for their PDHRA interviews. We are hopeful that more soldiers from this group will chose to participate in our study.

In an effort to increase our participation rate, Dr. Clarke suggested that we provide a flyer to soldiers highlighting our request for their participation in their PDHRA check-in packet. We will be submitting a modification for the flyer to the UW IRB and MRMC Headquarters for review soon.

Ft. Hood

Our subcontracted research team, headed by Dr. Elisa Borah, from STRONG STAR/UTHSCSA began recruiting soldiers in May 2013. So far the flow of soldiers through the PDHRA process at the SRP Center has been slow. To date, 102 soldiers have been recruited for our study. Dr. Borah has indicated that there will not be any large target groups for our study moving through the SRP Center until October 2013.

KEY RESEARCH ACCOMPLISHMENTS

To be determined after the Data Collection and Data Analysis phases are complete.

REPORTABLE OUTCOMES

To be determined after the Data Collection and Data Analysis phases are complete.

CONCLUSION

We are pleased to be collecting subject data at both at JBLM and at Ft. Hood. The process for reaching this stage has been long and complicated; however, we now have all IRB documentation in place and have a good working relationship with the SELF Center/PDHRA Clinic at JBLM, and at the SRP Center at Ft. Hood. Despite some of the continuing challenges of capturing a greater portion of the soldier flow through JBLM and the effects of the sequestration furloughs, we are hopeful that with a no-cost extension we will have success in reaching our target of 4,000 as soldiers return from deployment through 2014. Because of the delays, and also because of some fortunate budgetary circumstances for Dr. Vannoy and Ms. Flannery through the University of Washington, there are adequate monies available to continue with the project through 2014 should the NCE be approved.